



November 20, 2019

**VIA E-FILING**

The Honorable Leonard P. Stark  
U.S. District Court for the District of Delaware  
844 North King Street  
Wilmington, DE 19801

**FILED UNDER SEAL**

Re: *Vifor Fresenius Medical Care Renal Pharma Ltd., et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 18-390-LPS

Dear Chief Judge Stark:

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. ("Plaintiffs") submit this Letter in support of their Motion to Strike portions of Defendants Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. (collectively, "Defendants'") Opening Expert Report of Walter G. Chambliss, Ph.D. ("Chambliss Report") that rely on a prior art reference, Gerard K. Bolhuis and N. Anthony Armstrong, Excipients for Direct Compression –an Update, Pharmaceutical Development and Technology, 11:111-124, 2006 ("Bolhuis"), that was not disclosed by Defendants until they served the Chambliss Report on November 1, 2019. The portions of the Chambliss Report to be struck are attached as Exhibit A.

At the outset of this litigation, the Court entered the ESI Order (D.I. 30) and the Scheduling Order (D.I. 28) that collectively set a schedule governing the disclosure of prior art references and invalidity positions in this case. Defendants' Initial Invalidity Contentions were due on January 14, 2019 (D.I. 30), and absent agreement of the parties and approval of the Court, Defendants were required to "finally supplement, *inter alia*, the identification of...all invalidity references" by October 7, 2019. D.I. 28 and D.I. 124. Defendants timely served their Initial Invalidity Contentions on January 14<sup>th</sup>. Those contentions identify 24 prior art references, but the contentions make no mention of the Bolhuis reference. Similarly, on October 7<sup>th</sup>, the Defendants served an extensive supplementation of their invalidity contentions that identify an additional 22 prior art references for a total of 46 prior art references. Once again, Defendants' supplemental invalidity contentions make no mention of the Bolhuis reference. Thereafter, Defendants made no attempt to disclose Bolhuis at any point prior to the service of opening expert reports.

The Scheduling and ESI Orders provided an explicit deadline for identifying the prior art references that will be at issue in this case, and Defendants failed to comply with that deadline. Accordingly, Plaintiffs respectfully request that the Court strike the Bolhuis reference and the portions of the Chambliss Report that rely on Bolhuis. Fed. R. Civ. P. 37(c) ("If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.")

Fed. R. Civ. P. 37(c) precludes a party from relying on late-disclosed evidence "unless the failure was substantially justified or is harmless." In the Third Circuit, the *Pennypack* factors govern whether late-disclosed subject matter should be excluded: "(1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which

allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded.” *Integra LifeSciences Corp. v. Hyperbranch Medical Technology, Inc.*, 15-cv-819-LPS-CJB, 2018 WL 3814614, at \*1 (D. Del. Mar. 23, 2018) citing *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-05 (3d Cir. 1977). However, “[c]ourts applying the *Pennypack* factors in the case of sophisticated, complex litigation involving parties represented by competent counsel have been less indulgent in their application and more willing to exclude evidence without a strict showing that each of the *Pennypack* factors has been satisfied.” *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, 05-cv-132-JJF, 2007 WL 521894, at \*4 (D. Del. February 15, 2007).

“Prior art references must be disclosed during fact discovery,” and courts in the District of Delaware have excluded late-disclosed prior art and invalidity theories based on that art. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 03-cv-1158-SLR, 2005 WL 3159054, at \*4 (D. Del. Nov. 28, 2005)(refusing to change prior ruling excluding prior art references that “were not disclosed to plaintiffs by defendants until after the close of fact discovery.”); *see also Praxair, Inc. v. ATMI, Inc.*, 03-cv-01158-SLR, D.I. 231 at pp. 15-16 (D. Del. Nov. 8, 2005 (granting motion to strike portions of expert report relying on late disclosed prior art references); *Bridgestone Sports*, 2007 WL 521894, at \*4 (“Considering these circumstances, as well as the nature of the evidence sought to be precluded, the Court has concluded that Acushnet should be precluded from relying on its untimely disclosed prior art references.”); *Amgen Inc. v. Sanofi*, 14-cv-1317-SLR, D.I. 226 at 1 (D. Del. Feb. 18, 2016) (“The UTSW PCSK9 handout is excluded as being disclosed untimely.”). Ultimately, “[t]he decision to exclude evidence lies within the discretion of the Court.” *Bridgestone Sports*, 2007 WL 521894, at \*4.

Defendants’ decision to wait for opening expert reports to disclose Bolhuis is prejudicial to Plaintiffs for a number of reasons. This case is on a tight schedule in view of the 30 month stay, and Plaintiffs must now address a new invalidity theory in their responsive expert reports without having had the opportunity to conduct fact discovery on this theory and on a compressed schedule that leaves only 34 days from the time that Plaintiffs first became aware of the Bolhuis reference and the invalidity theories base on that reference. *See, e.g., Finch v. Hercules Inc.*, 92-251-MMS, 1995 WL 785100, at \*9 (D. Del. Dec. 22, 1995) (“[F]idelity to the constraints of Scheduling Orders and deadlines is critical to the Court’s case management responsibilities” and “flouting of discovery deadlines causes substantial harm to the judicial system.”).

Furthermore, the Plaintiffs were prejudiced in their selection of which claims to continue asserting in this litigation. At Defendants’ insistence, the parties entered into an agreement to streamline this litigation prior to opening expert reports. Under the parties’ agreement, Plaintiffs reduced the number of asserted claim to ten and Defendants reduced the number of prior art references being relied upon to twelve. In determining which claims to continue to assert, Plaintiffs relied in part on the invalidity defenses raised in Defendants’ Supplemental Invalidity Contentions. Plaintiffs cannot cure this prejudice. *See, e.g., Bridgestone Sports*, 2007 WL 521894, at \*3 (“Specifically, Bridgestone contends that it selected the claims it wishes to assert in this litigation based on the references in Acushnet’s contentions, and ‘[i]t is too late for Bridgestone to re-think its asserted claims in light of Acushnet’s attempt to change its invalidity contentions.’”). Defendants must adhere to the schedule in this case and cannot grant themselves an extension of time of their own accord.

Defendants contend that Plaintiffs are not prejudiced because Bolhuis is not “inconsistent” with their invalidity contentions. Under Defendants’ standard, it is difficult to imagine how any party would ever be prejudiced by late-disclosed prior art; it is unclear in what circumstances an additional prior art reference would be “inconsistent” with the position that a particular claim would have been obvious.

Defendants also have not provided any justification for their late disclosure. Instead, Defendants stated that Dr. Chambliss identified Bolhuis and that he may have done so after the supplemental contentions deadline. Defendants were unsure as to the exact timing and could provide no explanation as to why they waited until the opening expert report deadline to notify Plaintiffs of this new reference. Furthermore, Defendants retained Dr. Chambliss at least as early as May 1, 2019—Dr. Chambliss submitted declarations during claim construction—and Defendants have not explained why Dr. Chambliss was unable to identify the Bolhuis reference before the October 7, 2019 supplementation deadline nor have they described how they were diligent in seeking to identify the Bolhuis reference.

Finally, Defendants’ behavior with respect to the Bolhuis reference also warrants its exclusion. Defendants were acutely aware of the Court’s October 7, 2019 deadline for final supplementation of invalidity references yet they never sought leave of Court to add the Bolhuis reference after the deadline. Instead, Defendants, knowing the deadline had passed, sprung the Bolhuis reference on Plaintiffs in their opening expert report without any notice or explanation. If Defendants truly believed they had grounds to belatedly add the Bolhuis reference, Defendants should have moved the Court for leave to add it and provided Plaintiffs notice prior to Plaintiffs reducing claims and serving their opening expert reports. Sneaking a new invalidity reference in an expert report is not appropriate and Defendants invocation of the mantra “it’s easier to ask forgiveness than it is to get permission” is not well-taken or acceptable in litigation with known rules and long-set deadlines.

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: Counsel of Record (via E-Mail)